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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,006	10/25/2001	Bruce H. Morimoto	5412/1E887US2	4547

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/890,006

Applicant(s)

Morimoto

Examiner

Gollamudi Kishore

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 6) ☐ Other:

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## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

**1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

**2. Claims 1-4, 10 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**Claim 1 recites, “increasing the aqueous solubility of a pharmaceutically active agent”. What is conjugated to the active agent is a lipophilic phospholipid; that means the complex of a poorly water soluble compound is more lipophilic than the active compound itself. Then how can one increase the aqueous solubility? Clarification is requested.**

**The examiner suggests reciting the chemical name of DMP-323 in claims 10 and 15.**

### ***Claim Rejections - 35 USC § 102***

**3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless -**

**(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.**

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, 5, 11 and 16 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by Chasalow (5,830,432) of record.

Chasalow discloses methods of increasing the aqueous solubility of bioactive agent by conjugating them to phosphocholine moieties. According to Chasalow, any active agent could be used and those include steroids and aspirin (note the abstract, col. 2, line 25 through col. 4, line 65; examples and claims).

It would appear that many of the compounds do not appear to have support in the PCT application and support in the provisional application is also unclear. These rejections will be reconsidered, once the support in the priority papers is determined.

5. Claims 1, 2, 4 are rejected under 35 U.S.C. 102 (b) as being anticipated by Chasalow (5,703,063).

Chasalow discloses methods of increasing the solubility of bioactive agent in biological fluids by conjugating them to phosphocholine moieties. According to Chasalow, any active agent could be used and those taught include steroids and theophylline (abstract, col. 1, line 41 through col. 3, line 62, col. 5, lines 1-13, Examples and claims).

6. Claims 1-16 are rejected under 35 U.S.C. 102 (b) as being anticipated by WO 98/11906 of record.

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WO discloses methods of increasing the aqueous solubility of bioactive agent by conjugating them to phosphocholine moieties. The active agents taught by WO include claimed active compounds (abstract, page 2, line 30 through page 3, line 26; page 4, line 10 through page 7, line 5; Examples and claims).

7. Claims 4, 9 and 14 are rejected under 35 U.S.C. 102 (a) as being anticipated by Peterson (5,776,915).

Peterson discloses phosphocholine derivatives of retinoids (abstract, examples and claims).

*Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chasalow (5,830, 432) or Chasalow (5,703,063) or in combination.

The teachings of each of Chasalow's patents have been discussed above. What is lacking in both are the teachings of specific claimed compounds. However, in view of references' suggestion that the method is applicable to any active agent, it would have been obvious to one of ordinary skill in the art to use any active agent with the guidance provided by Chasalow with the expectation of obtaining similar results.

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What is lacking Chasalow (063) are the teachings of the phosphocholine to be phosphoserine and others. However, since the principle of preparation of complex is the same, it would have been obvious to one of ordinary skill in the art to use any phosphocholine; one would have been motivated to use the claimed phosphocholines in view of Chasalow (432) who teaches the claimed compounds for the same purpose.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

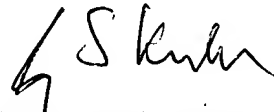
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is

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more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

*gsk*

August 5, 2003